PRD2008-01

Proposed Registration Decision

Trifloxystrobin

(publié aussi en français)

10 January 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 978-0-662-47574-3 (978-0-662-47575-0)
Catalogue number: H113-9/2008-1E (H113-9/2008-1E-PDF)

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Overview

Proposed Registration Decision for Trifloxystrobin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing conversion from conditional to full registration for Trifloxystrobin Technical Fungicide and end-use products Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide, containing the technical grade active ingredient trifloxystrobin for control of specific fungal diseases on turfgrass, ornamentals, grapes, pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince), wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats.

An evaluation of available scientific information found that, under the approved conditions of use, the end-use products have value and do not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Trifloxystrobin Technical Fungicide, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* is "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's a) efficacy; b) effect on host organisms in connection with which it is intended to be used; and c) health, safety and environmental benefits and social and economic impact."

information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

Before making a final registration decision on trifloxystrobin, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision document[4] on trifloxystrobin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Trifloxystrobin?

Trifloxystrobin is the active ingredient in the end-use products Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide. These products are used to control specific fungal diseases on turfgrass, ornamentals, grapes, pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince), wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats.

Health Considerations

Can Approved Uses of Trifloxystrobin Affect Human Health?

Trifloxystrobin is unlikely to affect your health when used according to the proposed label directions.

People could be exposed to trifloxystrobin when handling and applying the products. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when trifloxystrobin products are used according to label directions.

A toxicology assessment of trifloxystrobin, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide is presented in Regulatory Note REG2004-03, *Trifloxystrobin*.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation that would ingest the most trifloxystrobin relative to body weight, are expected to be exposed to less than 73% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from trifloxystrobin is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of trifloxystrobin is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

The required apple and grape field trial data, as presented in Regulatory Note REG2004-03, *Trifloxystrobin*, were submitted to the PMRA. Residue trials conducted throughout Canada and the United States using trifloxystrobin on grapes, pome fruits (apple, crabapple, loquat, pear, pear oriental and quince), wheat (winter, spring, hard red, durum, Canada prairie, soft white) spring barley and oats to support the use of trifloxystrobin are acceptable. No new MRLs for this active ingredient are being recommended.

A dietary risk assessment of trifloxystrobin, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide is presented in Regulatory Note REG2004-03, *Trifloxystrobin*.

Occupational Risks From Handling Trifloxystrobin

Occupational risks are not of concern when trifloxystrobin is used according to label directions, which include protective measures.

Farmers and custom applicators have potential for exposure to trifloxystrobin during mixing/loading and application to wheat, barley, oats, grapes and pome fruits. Lawn care operators, golf course and sod farm workers, and nursery and greenhouse operators have potential for exposure to trifloxystrobin during mixing/loading and application to turf and ornamentals. The occupational risks for these use scenarios are not of concern when the products are used according to label directions.

An occupational risk assessment of trifloxystrobin, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide is presented in Regulatory Note REG2004-03, *Trifloxystrobin*.

Environmental Considerations

What Happens When Trifloxystrobin is Introduced into the Environment?

The required long-term hydrolysis study conducted with the major transformation product, the chronic freshwater fish toxicity study conducted with the major transformation product and the dissipation/accumulation study on turf, as presented in Regulatory Note REG2004-03, *Trifloxystrobin*, were submitted to the PMRA.

Trifloxystrobin enters the environment when used as a fungicide on turfgrass, ornamentals and various food crops. Trifloxystrobin is non-persistent in soil and water, while its major transformation product is expected to be persistent in soil and water.

Although the use pattern of trifloxystrobin does not include direct application to water, the possibility that aquatic systems will be exposed to trifloxystrobin and its major transformation product, directly or indirectly, cannot be ruled out.

Laboratory studies indicated that the mobility of trifloxystrobin in soil is expected to be low to immobile and trifloxystrobin is not expected to leach through the soil profile beyond 30 cm; therefore, it is not expected to enter groundwater. The major transformation product is persistent in soil and is expected to have moderate to very high mobility in soils. Field studies indicate that it has the potential to leach under field conditions.

Based on low volatility, trifloxystrobin residues are not expected in the air.

The *n*-octanol–water partition coefficient of trifloxystrobin and its major transformation product indicate that these compounds have limited potential for bioaccumulation/bioconcentration in biological organisms.

Trifloxystrobin will pose a negligible risk to earthworms, honeybees and wild birds on an acute and dietary basis. However, the level of concern (LOC) is exceeded for wild mammals (based on dietary and chronic exposure), beneficial insects, wild birds on a reproductive basis, vascular plants, freshwater and marine invertebrates, freshwater algae and fish. Therefore, buffer zones to protect sensitive aquatic and terrestrial habitats are required during application. In addition, environmental hazard statements are required for protection of beneficial insects.

An environmental risk assessment of trifloxystrobin, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide is presented in Regulatory Note REG2004-03, *Trifloxystrobin*.

Value Considerations

What is the Value of Trifloxystrobin?

The required efficacy data for Flint 50 WG Fungicide confirming the lowest effective rate for the control of black rot disease (*Guignardia bidwellii*) on grapes, as presented in Regulatory Note REG2004-03, *Trifloxystrobin*, were submitted to the PMRA. An assessment of the available information supports the use of Flint 50 WG Fungicide for control of black rot disease on grapes.

Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide are used to control specific fungal diseases on turfgrass, ornamentals, grapes, pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince) and wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats.

A value assessment of Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide is presented in Regulatory Note REG2004-03, *Trifloxystrobin.*

Measures to Minimize Risk

Labels of registered pesticide product include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Key Risk-Reduction Measures

The current risk-reduction measures on the label of Trifloxystrobin Technical Fungicide, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide are adequate. No further risk-reduction measures are required.

Next Steps

Before making a final registration decision on trifloxystrobin, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision document, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

At the time the PMRA makes its registration decision, it will publish a Registration Decision document on trifloxystrobin (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

1.0 The Active Ingredient, Its Properties and Uses

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for a detailed assessment of the properties and uses for Trifloxystrobin Technical Fungicide, Stratego 250 EC Fungicide, Compass 50 WG Fungicide and Flint 50 WG Fungicide.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for a detailed assessment of the methods for analysis of Trifloxystrobin Technical Fungicide, Stratego 250 EC Fungicide, Compass 50 WG Fungicide and Flint 50 WG Fungicide.

2.2 Method for Formulation Analysis

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for a detailed assessment of the method for formulation analysis of Trifloxystrobin Technical Fungicide, Stratego 250 EC Fungicide, Compass 50 WG Fungicide and Flint 50 WG Fungicide.

2.3 Methods for Residue Analysis

The required enforcement analytical method for animal matrices (including a microwave extraction step to release the majority of bound residues), as presented in Regulatory Note REG2004-03, *Trifloxystrobin*, was submitted to the PMRA. The information submitted indicated the bound residues released by microwave extraction were not residues of concern.

Gas chromatography with nitrogen phosphorous detector (GC/NPD) method AG-659A was developed and proposed for data generation and enforcement purposes. This method fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices, environmental media and body fluids. Adequate extraction efficiencies were demonstrated using radiolabelled apple, peanut nutmeat, peanut hay, goat milk and poultry meat samples analysed with the enforcement method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for a detailed assessment of the toxicological database for Trifloxystrobin Technical Fungicide, Stratego 250 EC Fungicide, Compass 50 WG Fungicide and Flint 50 WG Fungicide.

3.2 Determination of Acceptable Daily Intake

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for information on the determination of acceptable daily intake for Trifloxystrobin.

3.3 Determination of Acute Reference Dose

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for information on the determination of the acute reference dose for trifloxystrobin.

3.4 Occupational and Residential Risk Assessment

Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for a detailed assessment of the occupational or bystander risk for end-use products Stratego 250 EC, Compass 50 WG and Flint 50 WG Fungicide.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The required apple and grape field trial data, as presented in Regulatory Note REG2004-03, *Trifloxystrobin*, were submitted to the PMRA. Supervised residue trials conducted throughout the United States and Canada using end-use products containing trifloxystrobin applied at label or higher rates in or on various crops are sufficient to support the proposed maximum residue limits.

The residue definition for risk assessment and enforcement in plant products and animal commodities is trifloxystrobin and the transformation product CGA-321113. The data gathering/ enforcement analytical methodology, AG-659A (GC/NPD), is valid for the quantification of trifloxystrobin and the transformation product CGA-321113 residues in plant and animal matrices. The residues of trifloxystrobin and the transformation product CGA-321113 are stable in plant and animal matrices when stored in a freezer at -18°C for at least 12 months.

3.5.2 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 1.3), which uses updated food consumption data from the United States Department of Agriculture's Continuing Survey of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The use of Flint 50 WG and Stratego 250 EC on pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince), grapes, wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats does not pose an unacceptable chronic dietary (both food and water) risk to any segment of the population, including infants, children, adults and seniors.

The refined chronic dietary exposure from all supported trifloxystrobin food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 29% of the acceptable daily intake (ADI). Aggregate exposure from food and water is considered acceptable. The PMRA estimates that chronic dietary exposure to trifloxystrobin from food and water is 24% of the ADI for the total population. The highest exposure and risk estimate is for all infants (<1 year) at 73% of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for trifloxystrobin consists of exposure from food and drinking water sources only; there are no residential uses.

3.5.4 Maximum Residue Limits

Refer to Regulatory Note REG2004-03, *Trifloxystrobin*, for the proposed maximum residue limits, the nature of the residues in animal and plant matrices, analytical methodology, field trial data, and the acute and chronic dietary risk estimates.

The trifloxystrobin MRLs proposed in Appendix II of the Regulatory Note have been presented for public consultation in publication PMRL2006-01, *Transitioning the Legal Establishment of Maximum Residue Limits (MRLs) for Pesticides from the Food and Drugs Act to the Pest Control Products Act: Consultation on Proposed MRLs*.

No new MRLs are being recommended at this time.

4.0 Impact on the Environment

Refer to Regulatory Document REG2004-03, *Trifloxystrobin* for a detailed assessment of the environmental impact of trifloxystrobin.

The required long-term hydrolysis study conducted with the major transformation product, the chronic freshwater fish toxicity study conducted with the major transformation product and the dissipation/accumulation study on turf, as presented in Regulatory Note REG2004-03, *Trifloxystrobin*, were submitted to the PMRA. The results of the studies confirm the conclusions presented in Regulatory Document REG2004-03, *Trifloxystrobin*.

4.1 Fate and Behaviour in the Environment

Refer to Regulatory Document REG2004-03, *Trifloxystrobin* for a detailed assessment of the fate and behaviour of trifloxystrobin in the environment.

The long-term hydrolysis study conducted with the major transformation product was found to be satisfactory. The submitted information confirms the stability of CGA-321113 to hydrolysis at environmentally relevant pHs and temperatures. Since the previous risk characterization assumed that CGA-321113 was stable to hydrolysis, no amendments to the previous risk assessment are required.

The dissipation/accumulation study of trifloxystrobin on turf was found to be satisfactory. In the information provided, trifloxystrobin has a half-life ranging from 8.6 to 20 days in turf and 11 days in soil. CGA-321113 is a major transformation product, with a half-life of 135 days and 124 days in turf and soil, respectively. CGA-373466 is another major transformation product in soil with a half-life of 47 days. The route of dissipation of trifloxystrobin in soil is primarily the transformation and isomerization to the CGA-321113 and the CGA-373466 transformation products. In turf, the major route of dissipation of trifloxystrobin is transformation and leaching to the soil. Trifloxystrobin did not leach beyond 7.5 cm and is not expected to enter groundwater. The CGA-321113 transformation product was detected throughout the soil profile to a depth of 45 cm in turf-covered soil, which is consistent with the results of other non-turf field studies and confirms that it has the potential to leach under field conditions.

4.2 Effects on Non-Target Species

To estimate the risk of potential adverse effects on non-target species, a quotient method is used. The risk quotient (RQ) is calculated by dividing the exposure estimate by a value representing a toxicity endpoint. A screening-level risk assessment is initially performed using the expected environmental concentrations (EECs) for a worst-case scenario (e.g. direct overspray of a body of water) and the most sensitive toxicity endpoint. Low risk is predicted if the RQ is less than the trigger value of one. In these cases, no further assessment is done. For those groups of organisms for which the RQ is greater than one, a refined assessment is undertaken. A refined assessment takes into consideration more realistic exposure scenarios (e.g. drift to non-target habitats and runoff to water bodies) and may consider different toxicity endpoints.

4.2.1 Effects on Terrestrial Organisms

Refer to Regulatory Note REG2004-03, *Trifloxystrobin*, for a detailed assessment of the effects on terrestrial organisms.

4.2.2 Effects on Aquatic Organisms

The submitted chronic freshwater fish study used to investigate the possibility of effects from long-term exposure to the major transformation product, CGA-321113, was found to be satisfactory.

The results of the prolonged toxicity test indicated that no sublethal effects were observed at any of the test concentrations at any point over the duration of the test. All endpoints yielded a no observable effects concentration (NOEC) of 100 mg a.i./L.

The screening level RQ for rainbow trout, *Oncorhynchus mykiss*, is less than 0.01. Therefore, the LOC is not exceeded for this organism at the proposed rate. Chronic effects on fish resulting from long-term exposure to CGA-321113 are not expected.

5.0 Value

Refer to Regulatory Document REG2004-03, *Trifloxystrobin* for a detailed assessment of the value and efficacy of trifloxystrobin.

The required efficacy data confirming the lowest effective rate of Flint 50 WG Fungicide for the control of black rot disease (*Guignardia bidwellii*) on grapes were submitted to the PMRA. These data consisted of four confirmatory black rot trials conducted in Canada between 2004 and 2005. Despite inoculations, disease did not develop in two of these trials and disease pressures were too low in the other two trials to adequately assess the product. In addition to the submitted efficacy data, the PMRA obtained additional efficacy data from other published, publicly available sources.

Based on the evidence originally submitted, the additional efficacy data submitted by the company, and the information obtained from published efficacy data, the current use claim for Flint 50 WG control of blackrot disease on grapes can be supported from an efficacy and value perspective.

Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide are acceptable to control selected fungal diseases on turfgrass, ornamentals, grapes, pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince) and wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, trifloxystrobin was assessed in accordance with PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of trifloxystrobin were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use products Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide.

Based on an assessment of the complete data package, the PMRA has reached the conclusion that these products do not meet TSMP Track 1 criteria. These products do not contain any USEPA or PMRA List 1 or 2 formulants. Refer to Regulatory Note REG2004-03, *Trifloxystrobin* for more detail.

7.0 Summary

7.1 Human Health and Safety

The toxicology database for Trifloxystrobin Technical Fungicide, Stratego 250 EC Fungicide, Compass 50 WG Fungicide and Flint 50 WG Fungicide is adequate and acceptable.

The nature of the residue in plants and animals is adequately understood. The residue definition for risk assessment and enforcement in plant products and animal commodities is trifloxystrobin and the transformation product CGA-321113. The use of trifloxystrobin on pome fruits, grapes, wheat, spring barley and oats does not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed. No new MRLs are being recommended at this time.

Mixers, loaders, applicators and workers entering treated areas are not expected to be exposed to levels of trifloxystrobin that will result in unacceptable risk when Stratego 250 EC Fungicide, Compass 50 WG Fungicide or Flint 50 WG Fungicide is used according to label directions. The personal protective equipment on the product labels is adequate to protect workers and no additional personal protective equipment is required.

7.2 Environmental Risk

Trifloxystrobin enters the environment when used as a fungicide on turfgrass, ornamentals and various food crops. Trifloxystrobin is non-persistent in soil and water, while its major transformation product is expected to be persistent in soil and water.

Although the use pattern of trifloxystrobin does not include direct application to water, the possibility that aquatic systems will be exposed to trifloxystrobin and its major transformation product, directly or indirectly, cannot be ruled out.

The mobility of trifloxystrobin in soil is expected to be low to immobile and this pesticide is not expected to leach through the soil profile beyond 30 cm; therefore, it is not expected to enter groundwater. The major transformation product is persistent in soil and is expected to have a moderate to very high mobility in soils. Field studies indicate that it has the potential to leach under field conditions.

Based on low volatility, trifloxystrobin residues are not expected in the air.

Trifloxystrobin and its major transformation product have limited potential for bioaccumulation/bioconcentration in biological organisms.

Trifloxystrobin will pose a negligible risk to earthworms, honeybees and wild birds on an acute and dietary basis. However, the level of concern (LOC) is exceeded for wild mammals (based on dietary and chronic exposure), beneficial insects, wild birds on a reproductive basis, vascular plants, freshwater and marine invertebrates, freshwater algae and fish. Therefore, buffer zones to protect sensitive aquatic and terrestrial habitats are required during application. In addition, environmental hazard statements are required for protection of beneficial insects.

7.3 Value

Trifloxystrobin is the active ingredient in the three end-use products, Compass 50 WG Fungicide, Flint 50 WG Fungicide and Stratego 250 EC Fungicide. These products can be used to control selected fungal diseases on turfgrass, ornamentals, grapes, pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince), wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient trifloxystrobin and the end-use products Compass 50 WG, Flint 50 WG and Stratego 250 EC Fungicide to control selected fungal diseases on turfgrass, ornamentals, grapes, pome fruits (apple, crabapple, loquat, mayhaw, pear, pear oriental and quince), wheat (winter, spring, hard red, durum, Canada prairie, soft white), spring barley and oats.

An evaluation of current scientific data from the applicant has resulted in the determination that, under the proposed conditions of use, the end-use products have value and do not present an unacceptable risk to human health or the environment.

List of Abbreviations

ADI	acceptable daily intake
cm	centimetre
DEEM	dietary exposure evaluation model
EC	emulsifiable concentrate
EEC	expected environmental concentration
FDA	*Food and Drugs Act*
GC/NPD	gas chromatography with nitrogen phosphorous detector
L	litre(s)
LOC	level of concern
MRL	maximum residue limit
NOEC	no observable effects concentration
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
RQ	risk quotient
WG	wettable granule

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Chemistry Assessment

PMRA Document Number	Reference
1119502	Response to the Pest Management Regulatory Agency's (PMRA) request for refinement of enforcement analytical method AG-659A as communicated in the PMRA's letter of August 5, 2003. 8 pages

2.0 Impact on Human and Animal Health

PMRA Document Number	Reference
383384	DACO 5.2
599407	COMPASS 50WG: Exposure (Occupational and/or Bystander - USC #30 - EP Summary
599895	Exposure Summary (Occupational and/or Bystander)--USC #14--EP
599896	Use Description/Scenario (Application and Post Application): STRATEGO 250EC Label
1029851	FLINT 50WG: Exposure (Occupational and/or Bystander) - USC #14 - EP Summary [Includes Pesticide Handlers Exposure Database Assessment (PHED)]
1119503	FLINT 50 WG - Magnitude of the Residue in/on Apples. Bayer Report No. 04BCS03. 305 pages.
1119504	FLINT 50 WG - Magnitude of the Residue in/on Grapes. Bayer Report No. 04BCS02. 179 pages.

3.0 Impact on the Environment

PMRA Document Number	Reference
1083898	2005, The Long Term Hydrolysis of CGA 321113 at Lower Temperatures: Response to the Canadian PMRA Regulatory Note for Trifloxystrobin (REG2004-03) January 30, 2004, DACO: 8.5
1083899	1997, Hydrolysis of [Trifluoromethyl-Phenyl-(U)- 14C] Labeled CGA 279202 Under Laboratory Conditions., 94UL04, DACO: 8.2.3.2
1083900	1996, Hydrolysis of (U)-)-14C-Phenyl-Glyoxylate Labeled CGA 279202 Under Laboratory Conditions., 94PK01, DACO: 8.2.3.2
1192605	2006, Terrestrial Soil Dissipation of Trifloxystrobin in Ontario Turf, 2002, FL022701, DACO: 8.3.2.1
1083901	1999, Prolonged Toxicity Test of CGA321113 (Metabolite of CGA279202) to Rainbow Trout (Oncorhynchus mykiss) Under Flow- Through Conditions., Study No. 983887, DACO: 9.5.3.1

4.0 Value

PMRA Document Number	Reference
1115905	Dornan, A. 2005. Flint 50 WG Fungicide (50% w/w trifloxystrobin). For control of Black Rot on Grapes. Bayer Crop Science, Project No. BYFCAN001, October 18, 2005.
1115905	Harrison, J., Sutton, T., and Anas, O. 2002. Control of fruit rot diseases on Chardonnay strobilurin fungicides. F & N Tests Vol 58: SMF025

B. ADDITIONAL INFORMATION CONSIDERED

I) Published Information

Value

PMRA Document Number	Reference
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1378889	Wilcox, W.F. and Riegel, D.G.. 2001. Evaluation of fungicides for control of grape black rot. F & N Tests Vol 57: SMF22.